工厂长

APR 2.8 2008

Dkt No. 2251/75191/JPW/BJA

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Stan Gronthos et al.

Serial No. : 10/551,326 Group Art Unit: 1633

Filed: March 30, 2006 Examiner: K.T. Hiriyanna

Title : PERIVASCULAR MESENCHYMAL PRECURSOR CELL INDUCED

BLOOD VESSEL FORMATION

1185 Avenue of the Americas New York, New York 10036 April 24, 2008

MAIL STOP AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following items, which are listed on the Substitute Form PTO-1449 attached hereto as Exhibit A. Items 1-27 are related U.S. Patent and Patent Application Publications. No copies of these items are attached hereto as permitted by 37 C.F.R. §1.98(a)(2)(ii). Copies of items 28-119 are attached hereto as Exhibits 1-92, respectively:

- U.S. Patent No. 5,197,985 issued to Caplan et al. on March 30, 1993;
- U.S. Patent No. 5,226,914 issued to Caplan et al. on July 13, 1993;

Serial No.: 10/551,326

Filed: March 30, 2006

- U.S. Patent No. 5,486,359 issued to Caplan et al. on January 23, 1996;
- 4. U.S. Patent No. 5,591,625 issued to Gerson et al. on January 7, 1997;
- U.S. Patent No. 5,811,094 issued to Caplan on September 22, 1998;
- 6. U.S. Patent No. 5,827,740 issued to Pittenger on October 27, 1998;
- 7. U.S. Patent No. 5,837,539 issued to Caplan et al. on November 17, 1998;
- U.S. Patent No. 5,922,597 issued to Verfaillie et al. on July 13, 1999;
- 9. U.S. Patent No. 6,022,540 issued to Bruder et al. on February 8, 2000;
- 10. U.S. Patent No. 6,087,113 issued to Caplan et al. on July 11, 2000;
- 11. U.S. Patent No. 6,261,549 issued to Fernandez et al. on
  July 17, 2001;
- 12. U.S. Patent No. 6,322,784 issued to Pittenger et al. on November 27, 2001;
- 13. U.S. Patent No. 6,335,195 issued to Rodgers et al. on January 1, 2002;
- 14. U.S. Patent No. 6,387,367 issued to Davis-Sproul et al. on
  May 14, 2002;
- 15. U.S. Patent No. 6,387,369 issued to Pittenger et al. on May 14, 2002;
- 16. U.S. Patent No. 6,645,727 issued to Thomas et al. on November 11, 2003;
- 17. U.S. Patent No. 6,709,864 issued to Pittenger et al. on March 23, 2004;

Serial No.: 10/551,326

Filed: March 30, 2006

- 18. U.S. Patent No. 6,875,430 issued to McIntosh et al. on April 5, 2005;
- 19. U.S. Patent No. 7,122,178 issued to Simmons et al., on October 17, 2006;
- 20. U.S. Patent No. 5,405,772 issued to Ponting et al., April
  11, 1995;
- 21. U.S. Patent Application Publication No. 2004-0107453, published June 3, 2004;
- 22. U.S. Patent Application Publication No. 2006-0008452 published January 12, 2006;
- 23. U.S. Patent Application Publication No. 2005-0019911 published January 27, 2005;
- 24. U.S. Patent Application Publication No. 2005-0158289 published July 21, 2005;
- 25. U.S. Patent Application Publication No. 2005-0281790 published December 22, 2005;
- 26. U.S. Patent Application Publication No. 2002-0085996, published July 2002;
- 27. U.S. Patent Application Publication No. 2006-0193840 Alpublished August 31, 2006;
- 28. PCT International Publication No. WO 01/011011, published February 15, 2001; (Exhibit 1)
- 29. PCT International Publication No. WO 04/84921 A1, published October 7, 2004; (Exhibit 2)
- 30. PCT International Application Publication No. WO 04/85630
  Al published October 7, 2004; (Exhibit 3)
- 31. Alberico et al. (1987) Blood 69, page 1120; (Exhibit 4)
- 32. Allen, T.D., (1981) "Haemopoietic Microenvironments in vitro: ultrastructural aspects" CIBA Found. Symposium 84, pages 38-67; (Exhibit 5)

Serial No.: 10/551,326

Filed: March 30, 2006

- 33. Allen et al. (1990) "Marrow Biology and Stem Cells" Immunol. Ser. 49, pages 1-38; (Exhibit 6)
- 34. Anklesaria et al. (1989) Blood 74, page 1144; (Exhibit 7)
- 35. Anklesaria et al. (1987) Proc. Nat'l Acad. Sci. USA 84, page 7681; (Exhibit 8)
- 36. Bennett, J.H. et al. (1991) J. Cell Sci. 99(1), page 131; (Exhibit 9)
- 37. Bentley, S.A. (1982) Br. J. Haematol 50(1), pages 1-6; (Exhibit 10)
- 38. Castro-Malaspina et al. (1980) "Characterization of Human Bone Marrow Fibroblast Colony-Forming Cells and Their Progeny" Blood 56, pages 289-301; (Exhibit 11)
- 39. Castro-Malaspina et al. (1981) "Human Megakaryocyte Stimulation of Proliferation of Bone Marrow Fibroblasts" Blood 57, pages 781-787; (Exhibit 12)
- 40. Clarke, Emer, "Mesenchymal Cells" www.stemcell.com (minireview); (Exhibit 13)
- 41. Dexter et al. (1977) "Conditions Controlling the Proliferation of Haemopoietic Stem Cells in Vitro" J. Cell Physiol. 91, pages 335-344; (Exhibit 14)
- 42. Dexter et al. (1984) Kroc Found. Ser. 18, pages 57-96; (Exhibit 15)
- 43. Doherty, M.J. et al. (1998) "Vascular Pericytes Express
  Osteogenic Potential In Vitro and In Vitro" J. Bone and
  Mineral Research 13, pages 828-838; (Exhibit 16)
- 44. Fong et al. (1997) "Nonradioactive, Agarose Minigel Procedure for Telomeric Repeat Amplification Protocol" BioTechniques 23, pages 1029-1032; (Exhibit 17)
- 45. Friedenstein (1976) Int'l R. Cytology 47, pages 327-359; (Exhibit 18)

Serial No.: 10/551,326

Filed: March 30, 2006

- 46. Friedenstein (1980) "Stromal Mechanisms of Bone Marrow: Cloning in Vitro and Retransplantation in Vivo" Immunology of Bone Marrow Transplantation, pages 19-29 Haematol. Blood Transfusion; (Exhibit 19)
- 47. Friedenstein et al. (1970) "The Development of Fibroblast Colonies in Monolayer Cultures of Guinea-Pig Bone Marrow and Spleen Cells" Cell Tissue Kinetics 3, pages 393-403; (Exhibit 20)
- 48. Friedenstein et al. (1992) Bone and Mineral 18, pages 199-213; (Exhibit 21)
- 49. Gronthos, S. et al. (2002) "Stem Cell Properties of Human Dental Pulp Stem Cells" J. Dent. Res. 81(8), pages 531-535; (Exhibit 22)
- 50. Gronthos, S., et al. (1994) "The STRO-1+ Fraction of Adult Human Bone Marrow Contains the Osteogenic Precursors," Blood 84, pages 4164-4173; (Exhibit 23)
- 51. Gronthos, S., et al. (1995) Blood 85, pages 929-940; (Exhibit 24)
- 52. Huang and Terstappen (1992) Nature 360, pages 745-749; (Exhibit 25)
- 53. Keating et al. (1982) Nature 298, pages 280-283; (Exhibit 26)
- 54. Kim et al. (1994) Science 266, pages 2011-2015; (Exhibit 27)
- 55. Knospe et al. (1966) Blood 28, pages 398-415; (Exhibit 28)
- 56. Knospe et al. (1972) Blood 39, pages 331-340; (Exhibit 29)
- 57. Lichtman (1981) Experimental Hematology 9, page 391-410; (Exhibit 30)
- 58. Long (1992) Experimental Hematology 20, pages 288-301; (Exhibit 31)

Serial No.: 10/551,326

Filed: March 30, 2006

- 59. McManus and Weiss (1984) Blood 64, pages 1036-1041; (Exhibit 32)
- 60. McIntyre and Bjornson (1986) Exp. Hematol. 14, pages 833-839; (Exhibit 33)
- 61. Miltenyi et al. (1990) Cytometry 11, pages 231-238; (Exhibit 34)
- 62. Owen (1985) Bone and Mineral Research 3, pages 1-25; (Exhibit 35)
- 63. Owen and Friedenstein (1988) CIBA Found. Symposium 136, pages 42-60; (Exhibit 36)
- 64. Perkins and Fleischman (1990) Blood 75, pages 620-625; (Exhibit 37)
- 65. Piersma et al. (1983) Br. J. Haematol. 54, pages 285-290; (Exhibit 38)
- 66. Rothstein et al. (1985) Blood 65, page 744; (Exhibit 39)
- 67. Simmons and Gronthos (1991) Int'l J. of Cell Cloning 9, page 408 (abstract); (Exhibit 40)
- 68. Simmons, P.J., et al. (1994) "Isolation, Characterization and Functional Activity of Human Marrow Stromal Progenitors in Hemopoiesis" Advances in Bone Marrow Purging and Processing: Progress in Clinical and Biological Research; Fourth Int'l Symposium 389, pages 271-280; (Exhibit 41)
- 69. Simmons et al. (1987) Nature 328, pages 429-432; (Exhibit 42)
- 70. Simmons and Torok-Storb (1991) Blood 78, pages 55-62; (Exhibit 43)
- 71. Simmons and Torok-Storb (1991) Blood 78, pages 2848-2853; (Exhibit 44)
- 72. Tavassoli and Friedenstein (1983) Ann. J. Hematol. 15, pages 195-203; (Exhibit 45)

Serial No.: 10/551,326

Filed: March 30, 2006

- 73. Tavassoli and Crosby (1968) Science 161, pages 54-56; (Exhibit 46)
- 74. Testa et al. (1988) "Long-Term Bone Marrow Damage After Cytotoxic Treatment: Stem Cells and Microenvironment in Hematopoiesis: Long-Term Effects of Chemotherapy and Radiation" Hematol. Published by Marcel & Deaker, Inc. 8, pages 75-91; (Exhibit 47)
- 75. Van Vlasselaer et al. (1994) Blood 84, pages 753-763; (Exhibit 48)
- 76. Waller et al. (1995) Blood 85, pages 2422-2435; (Exhibit 49)
- 77. Weiss (1976) Anatomical Record 186, pages 161-184; (Exhibit 50)
- 78. Axelrad et al., New Technologies for the Enhancement of Skeletal Repair, Injury, Int. J. Care Injured (2007) 38S1:S49-S62; (Exhibit 51)
- 79. Bruder et al., Mesenchymal Stem Cells in Bone Development,
  Bone Repair, and Skeletal Regeneration Therapy, J. Cell
  Biochem; (1994) 56:283-294; (Exhibit 52)
- 80. Dennis et al., Osteogenesis in Marrow-Derived Mesenchymal Cell Porous Ceramic Composites Transplanted Subcutaneously: Effect of Fibronectin and Laminin on Cell Retention and Rate of Osteogenic Expression, Cell Transplant (1992) 1:23-32, Abstract; (Exhibit 53)
- 81. Zvaifler, et al., (2000) "Mesenchymal precursor cells in the blood of normal individuals," Arthritis Research and Therapy, 2: 477-488; (Exhibit 54)
- 82. Ji, et al., (2004) "Interactions of Chemokines and Chemokine Receptors Mediate the Migration of Mesenchymal Stem Cells to the Impaired Site in the Brain After

Serial No.: 10/551,326

Filed: March 30, 2006

Page 8

Hypoglossal Nerve Injury," Stem Cells, 22: 415-427; (Exhibit 55)

- 83. Sordi, et al., (2005) "Bone marrow mesenchymal stem cells express a restricted set of functionally active chemokine receptors capable of promoting migration to pancreatic islets," Blood, 106(2): 419-427; (Exhibit 56)
- 84. Wynn, et al., (2004) "A small proportion of mesenchymal stem cells strongly expresses functionally active CXCR4 receptor capable of promoting migration to bone marrow," Blood, 104(9): 2643-2645; (Exhibit 57)
- 85. Kortesidis, et al., (2005) "Stromal-derived factor-1 promotes the growth, survival, and development of human bone marrow stromal stem cells," Blood, 105(10): 3793-3801; (Exhibit 58)
- 86. Gronthos, S., et al., (1999) "Differential Cell Surface Expression Of The STRO-1 And Alkaline Phosphatase Antigens On Discrete Developmental Stages In Primary Culture Of Human Bone Cells," Journal of Bone and Mineral Research, 14(1): 47-56; (Exhibit 59)
- 87. Stewart, K., et al., (1999) "Further Characterization Of Cells Expressing STRO-1 In Cultures Of Adult Human Bone Marrow Stromal Cells," Journal of Bone and Mineral Research, 14(8): 1345-1356; (Exhibit 60)
- 88. International Search Report issued by the International Searching Authority (ISA/AU) on May 17, 2004 in connection with International Application No. PCT/AU2004/000416; (Exhibit 61)
- 89. International Preliminary Report on Patentability issued by the International Bureau of WIPO on October 1, 2005 in

Serial No.: 10/551,326

Filed: March 30, 2006

- connection with International Application No. PCT/AU2004/000416; (Exhibit 62)
- 90. International Search Report issued by the International Searching Authority (ISA/AU) on August 22, 2005 in connection with International Application No. PCT/AU2005/000953; (Exhibit 63)
- 91. International Search Report issued by the International Searching Authority (ISA/AU) on November 25, 2005 in connection with International Application No. PCT/AU2005/001445; (Exhibit 64)
- 92. Office Action issued January 12, 2005 in connection with U.S. Serial No. 10/030,411; (Exhibit 65)
- 93. Office Action issued June 28, 2005 in connection with U.S. Serial No. 10/030,411; (Exhibit 66)
- 94. Final Office Action issued January 9, 2006 in connection with U.S. Serial No. 10/030,411; (Exhibit 67)
- 95. Office Action issued April 20, 2007 in connection with U.S. Serial No. 10/955,709; (Exhibit 68)
- 96. Office Action issued August 24, 2007 in connection with 11/178,920; (Exhibit 69)
- 97. Office Action issued August 25, 2006 in connection with U.S. Serial No. 10/955,709; (Exhibit 70)
- 98. Examiner Interview Summary issued June 27, 2006 in connection with U.S. Serial No. 10/030,411; (Exhibit 71)
- 99. Office Action issued August 24, 2007 in connection with U.S. Serial No. 11/178,920; (Exhibit 72)
- 100. Office Action issued December 15, 2006 in connection with U.S. Serial No. 11/178,920; (Exhibit 73)
- 101. Office Action issued July 10, 2006 in connection with U.S. Serial No. 11/178,920; (Exhibit 74)

Serial No.: 10/551,326

Filed: March 30, 2006

- 102. Office Action issued January 22, 2007 in connection with U.S. Serial No. 11/169,875; (Exhibit 75)
- 103. Office Action issued July 10, 2006 in connection with U.S. Serial No. 10/813,747; (Exhibit 76)
- 104. Office Action issued December 15, 2006 in connection with U.S. Serial No. 10/813,747; (Exhibit 77)
- 105. Office Action issued April 3, 2007 in connection with U.S. Serial No. 10/813,747; (Exhibit 78)
- 106. Office Action issued October 19, 2007 in connection with U.S. Serial No. 10/813,747; (Exhibit 79)
- 107. Restriction Requirement issued January 8, 2008 in connection with U.S. Serial No. 10/551,162; (Exhibit 80)
- 108. Final Office Action issued January 10, 2008 in connection with U.S. Serial No. 10/955,709; (Exhibit 81)
- 109. Restriction Requirement issued January 8, 2008 in connection with U.S. Serial No. 11/326,736; (Exhibit 82)
- 110. Extended European Search Report issued December 27, 2007 in connection with European Application No. 05787106.3; (Exhibit 83)
- 111. Supplementary European Search Report issued January 2, 2008 in connection with European Application No. 05754008.0; (Exhibit 84)
- 112. Cochlovius, B. et al. (2003) "Therapeutic Antibodies,"

  Modern Drug Discovery pp 33-34, 37-38; (Exhibit 85)
- 113. Gronthos et al. Journal of Hematotherapy, 1996. 5, 15-23 (Abstract); (Exhibit 86)
- 114. Hansson, M. et al. (2007) "Commentary: Isolated Stem Cells
   Patentable as Cultural Artifacts?" V.25, pp. 1507-1510;
   (Exhibit 87)
- 115. Pan, Beiging et al. (2004) "The nitrogen-containing

Serial No.: 10/551,326

Filed: March 30, 2006

Page 11

bisphosphonate, zaledronic acid, increases mineralisation of human bone-derived cells in vitro." Bone 34:112-123; (Exhibit 88)

- 116. Cassiede, P. et al. (1996) "Osteochondrogenic Potential of Marrow Mesenchymal Progenitor Cells Exposed to TGF- ß1 or PDGF-BB as Assayed In Vivo and In Vitro" Journal of Bone and Mineral Research Vol. 11(9):1264-1273; (Exhibit 89)
- 117. Kang Yong Jung et al. (2004) "Involvement of PI-3-kinase, JNK, PKC, and PKA in the PDGF-induced proliferation in human adipose tissue-derived mesenchymal stem cells" Vol. 18(8) Pg. C253; (Exhibit 90)
- 118. U.S. Serial No. 11/663,570, filed March 23, 2007; (Exhibit 91) and
- 119. U.S. Serial No. 11/663,563, filed March 23, 2007. (Exhibit 92)

Item 115 was cited in an Extended European Search Report issued December 27, 2007 in connection with European Application No. 05787106.3, a copy of which is attached hereto as **Exhibit 83**.

Items 20, 116 and 117 were cited in Supplementary European Search Report issued January 2, 2008 in connection with European Application No. 05754008.0, a copy of which is attached hereto as Exhibit 84.

This Supplemental Information Disclosure Statement is being submitted under 37 C.F.R. §1.97(b)(3) before the issuance of a first Office Action on the merits. The Examiner is respectfully requested to make these items of record in the

Serial No.: 10/551,326

Filed: March 30, 2006

Page 12

present application by initialing and returning a copy of the enclosed Substitute Form PTO-1449.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

MAIL STOP AMENDMENT Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

John P. White Red. No. 28,678 Date

John P. White

Registration No. 28,678
Attorney for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036

(212) 278-0400